

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure
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For: VARIABLE VALVE APPARATUS AND METHODS

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Remarks

The Final Office Action mailed 17 July 2006 has been received and reviewed. Applicants are presenting an amendment to claim 26, leaving claims 1-9 and 11-30 pending. Reconsideration and withdrawal of the rejections are respectfully requested.

Entry of Amendment

Entry of the proposed amendment to claim 26 is respectfully requested to place the rejected claims in better form for consideration on appeal. Furthermore, Applicants respectfully submit that as claim 26 was newly presented in the previous response filed on 29 June 2006, the amendment to correct this typographical error could not have been presented earlier.

Objection to the Drawings

The Examiner objected to the drawings under 37 CFR 1.83(a). Specifically, it was noted that the drawings must show every feature of the invention specified in the claims. Therefore, the Examiner has recommended that the "located closer" (claim 26) must be shown or the feature(s) canceled from the claim(s).

After review, Applicants note that the basis for this objection lies in the typographical error that Applicants are seeking to correct with the proposed amendment to claim 26. If the amendment is entered, claim 26 will recite "that the first process chamber is located closer to the center than the second process chamber." This feature is depicted in the figures (*see, e.g.*, Figures 1 and 3A-3D, as described in the specification at p. 6, line 1 to p. 7, line 9 and p. 9, line 31 to p. 10, line 24) and, thus, addresses the objection to the drawings as set forth by the Examiner.

Entry of the amendment to claim 26 and withdrawal of the objection to the drawings are, therefore, respectfully requested.

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The 35 U.S.C. §112, Second Paragraph, Rejections

The Examiner rejected claims 1-9 and 11-30 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Terms "Valved" and "Valve":

It was asserted in the Office Action that, "[a]s to claims 1-30, the terms 'valved' and 'valve' are confusing, as the written specification and disclosure seems to describe a wall 64 in which an opening if (*sic*) formed by a laser, and not a valve." *Final Office Action*, p. 3 (July 17, 2006). As further support for this rejection, it is also asserted that "[t]he term 'valve' is not consistent with its regular meaning. After all, valves are reusable, and the disclosed creation of an opening in the wall 64 is not. Valves include seats and valve members. Puncturing a hole in the side of a pool does not suggest a valve. It merely suggests a broken liner." *Id.* Applicants respectfully submit that this reasoning is insufficient to support a rejection under § 112, second paragraph.

At the outset, Applicants note that the terms "valved" and "valve" are addressed in connection with this rejection as if the terms were recited alone in the claims. That is not, however, the case. In fact, the terms "valved" and "valve" are used to modify a noun. Claims 1-9 and 11-30 recite (in order of appearance) a "valved process chamber", "valve chamber", "valve septum", and "valve lip". In other words, the claims use "valve" or "valved" in the form of an adjective to describe a feature (e.g., process chamber, chamber, septum, or lip) that is a part of the fluid control structures. This distinction has not been addressed in either of the last two Office Actions and, Applicants submit, is one reason for reconsideration and withdrawal of this rejection.

In addition to failing to address the actual language of the rejected claims, the proper standard has not been applied. The proper standard to apply in assessing a claim under 35 U.S.C. § 112, second paragraph, is whether the claim as a whole "apprises one of ordinary skill in the art

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of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent." M.P.E.P. §2173.02, p. 2100-213 (8th Ed., Rev. 3, August 2005).

The reasoning presented as to why the use of the terms "valve" and "valved" in the claims does not meet the requirements of § 112, second paragraph is, essentially, that "valves are reusable" and that "[v]alves include seats and valve members". No support is offered for these limited definitions of what can constitute a valve. In addition, it is asserted that "[p]uncturing a hole in the side of a pool does not suggest a valve. It merely suggests a broken liner." Applicants respectfully submit that these assertions do not meet the standards for a proper § 112, second paragraph rejection.

As noted in Applicants' previous responses, the art cited in now-withdrawn rejections under 35 U.S.C. §§ 102 & 103 also uses the terms "valve" and "valved" to describe features that cannot be open and closed or reused. As a result, Applicants submit that this is strong evidence that Applicants' use of the terms "valved" and "valve" would not render the claims indefinite to those of ordinary skill in the art.

Claim 23:

Claim 23 is also rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention because it is asserted that the "preamble is not consistent with the body" of the claim.

As support for this rejection, it is asserted that "the body (after 'comprising', line 1) calls for a plurality of unconnected arrays, suggestive of an aggregation of parts." Outside of a rhetorical question, no reasoning is presented as to why or how one of ordinary skill in the art would not understand that the sample processing devices of claim 23 would include a plurality of process arrays formed therein.

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Applicants also note that claim 23 actually recites " a plurality of process arrays" not a "plurality of unconnected process arrays" as discussed in support of the rejection of claim 23.

Further, this rejection does not address the various features of each process array that are provided in the sample processing device such as, e.g., "a first process chamber that comprises a process chamber volume located between opposing first and second major sides of the sample processing device, wherein the first process chamber occupies a first process chamber area on the sample processing device." Other features of the process arrays are also recited as being within the sample processing device, e.g., "a valve chamber located within the first process chamber area, the valve chamber located between the first process chamber volume and the second major side of the sample processing device." In view of these recitations placing the features of the process arrays within a single sample processing device, any assertions that one of ordinary skill in the art would be confused by the asserted inconsistency between the preamble and the body of claim 23 cannot be maintained.

Applicants respectfully submit that the requirements for a rejection of claim 23 under 35 U.S.C. § 112, second paragraph has not been presented.

For at least the above reasons, Applicants respectfully submit that claims 1-9 and 11-30 do meet the requirements of § 112, second paragraph. Reconsideration and withdrawal of the rejection of claims 1-9 and 11-30 are, therefore, respectfully requested.

The 35 U.S.C. §102 Rejection

Claims 14, 16, 17, and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Godec et al. (U.S. Patent No. 5,976,468). This rejection is respectfully traversed.

Applicants submit that Godec et al. does not disclose, *inter alia*, either "detecting a characteristic of the sample material in the process chamber through the detection window" or "forming an opening in the valve septum at a selected location along the length of the process

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chamber, wherein the selected location is correlated to the detected characteristic of the sample material" as recited in claim 14 (from which claims 16, 17, and 20 depend).

These deficiencies were noted in Applicants' previous submissions. In response, it is asserted in the most recent Final Office Action that "the chamber is typically a 'test tube' (col. 8, line 17), which passes electromagnetic energy there through, permitting liquid level to be seen as it leaves the container." *Final Office Action*, p. 4 (July 17, 2006). Applicants note, however, that these assertions do not support a finding that Godec et al. teaches the steps recited in claim 14.

For example, there is no discussion as to how Godec et al. teaches "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material" as recited in claim 14. Rather, the needles 70 and 100 of Godec et al. will always pierce the membrane 94 at the same location and the openings in those needles will always be in the same location, regardless of any detected characteristic of material in the test tube 90.

If it is the intention of the Examiner to rely on inherency in support of the rejection of method claims 14, 16, 17, and 20, Applicants submit that the rejection fails to meet the requirements set for an anticipation rejection based on inherency, i.e., "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *M.P.E.P.* § 2112, p. 2100-57, 8th Ed., Rev. 3, (August 2005) (emphasis in original) (citing *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). No such basis has been provided to support this rejection.

These shortcomings of the anticipation rejection of claims 14, 16, 17, and 20 were discussed in Applicants' previous response, but were not addressed in the most recent Office Action. In the event this rejection is maintained, Applicants respectfully request that these

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features of the method recited in claims 14, 16, 17, and 20 be discussed so that Applicants can respond.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the anticipation rejection of claims 14, 16, 17, and 20 in view of Godec et al.

The 35 U.S.C. §103 Rejections

Claims 14, 16, 17, and 20

Claims 14, 16, 17, and 20 were rejected under 35 U.S.C. §103 as being obvious over Godec et al. (U.S. Patent No. 5,976,468). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Applicants noted above with respect to the anticipation rejection of independent method claim 14 that Godec et al. does not teach, e.g., "detecting a characteristic of the sample material in the process chamber through the detection window." Nor does Godec et al. teach "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material." Further, the Office Action provides no assertions as to why or how one of ordinary skill in the art would modify the teachings of Godec et al. to include the missing elements as would be required for a *prima facie* case of obviousness.

For at least these reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claims 14, 16, 17, and 20. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

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Claim 21

Claim 21 was also rejected under 35 U.S.C. §103(a) as being unpatentable over Godec et al. (U.S. Patent No. 5,976,468). This rejection is respectfully traversed.

Claim 21 depends from independent claim 14. Applicants noted above with respect to the anticipation and obviousness rejections of independent method claim 14 that Godec et al. does not teach or suggest, e.g., "detecting a characteristic of the sample material in the process chamber through the detection window." Nor does Godec et al. teach or suggest "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material." Further, the portion of the Office Action setting forth the obviousness rejection of claim 21 does not discuss how or why one of ordinary skill in the art would modify the teachings of Godec et al. to include the missing elements as would be required for a *prima facie* case of obviousness of claim 21 in view of Godec et al.

For at least these reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claim 21. Reconsideration and withdrawal of the obviousness rejection of claim 21 are, therefore, respectfully requested.

Claims 23, 24, and 25

Claims 23, 24, and 25 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Godec et al. (U.S. Patent No. 5,976,468). This rejection is respectfully traversed.

Claim 23 is an independent article claim and claims 24 and 25 each depend directly from independent claim 23. It is asserted in support of the rejection of claim 23 that the "comments existing above as to claim 14 similarly apply here." *Final Office Action*, p. 4 (July 17, 2006). Applicants respectfully submit that reliance on the comments with respect to method claim 14 do not address why or how one of ordinary skill in the art would find the invention recited in article claim 23 obvious.

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For example, claim 23 recites features that are not recited in method claim 14 such as "a conduit" and "a second process chamber". In the absence of any discussion as to where Godec et al. teaches these features or how/why one of ordinary skill in the art would be motivated to modify the teachings of Godec et al. to reach the invention of claim 23, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claim 23 (or its dependent claims 24 and 25).

In addition, claim 23 also recites that the sample processing device includes "a plurality of process arrays". It is asserted in support of the rejection of claim 23 that "it would have been obvious to employ two (20) of Godec's devices 10 on the same table to permit two operators to conveniently provide for two tests on two samples at the same time." *Final Office Action*, pp. 4-5 (July 17, 2006). Applicants respectfully submit that merely placing two of the devices described in Godec et al. on a table does not support a *prima facie* case of obviousness for a variety of reasons.

For example, claim 23 recites, among other things, that "each process array of the plurality of process arrays" includes a "a first process chamber that comprises a process chamber volume located between opposing first and second major sides of the sample processing device" and a "valve chamber located between the first process chamber volume and the second major side of the sample processing device."

Support for the obviousness rejection of claim 23 is limited to the assertion that placing two of the Godec et al. devices on a table would be obvious because it would "permit two operators to conveniently provide for two tests on two samples at the same time." *Final Office Action*, p. 5 (July 17, 2006). No discussion is provided, however, as to how the process chambers and valve chambers in two of the Godec et al. devices could be considered as located between the first and second major sides of one sample processing device as recited in claim 23. Applicants respectfully submit that no such discussion is provided because no reasoned basis for any such assertions can be found.

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With respect to claims 24 and 25, both of which depend from independent claim 23, Applicants note no discussion is provided as to where or how Godec et al. discloses or suggests the loading chambers and conduits recited in claims 24 and 25. As a result, Applicants respectfully a *prima facie* case of obviousness has not been established with respect to claims 24 and 25.

For at least these reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claims 23, 24, and 25. Reconsideration and withdrawal of the obviousness rejection of claims 23, 24, and 25 are, therefore, respectfully requested.

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Summary

It is respectfully submitted that the pending claims 1-9 and 11-30 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of October, 2006, at 12:10 PM (Central Time).

By: KW RaaschName: KEVIN W. RAASCH